INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number		10539505
Filing Date		2010-03-31
First Named Inventor Jorg F		Rosenberg et al.
Art Unit		1621
Examiner Name Katak		am, Sudhakar
Attorney Docket Number		M/43212-US-1

U.S.PATENTS						
miner	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
K/	1	6221395	B1	2001-04-24	Jagotec AG	
	2	6465011	B2	2002-10-15	Abbot Laboratories	
	3	6558699	B2	2003-05-06	SmithKline Beecham Corporation	
	4	4772605		1988-09-20	Naik et al.	
,	5	5554789		1996-09-06	Carganico et al.	
K	6	4925676		1990-05-15	Warner-Lambert Company	
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			U.S.P.	ATENT APPLIC	CATION PUBLICATIONS	
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	√√ u wisi	2 3 4 4 5 6 u wish to ac	Patent Number No Patent Number () 1 6221395 2 6465011 3 6558699 4 4772605 5 5554789 6 4925676 u wish to add additional U.S. Paten	No Patent Number Code1		Name of Patentee or Applicant Saue Date Name of Patentee or Applicant of cited Document

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/SK/	1	20080051411	A1	2008-02-28	Cink, et al.	
	2	20060280790	A1	2006-12-14	Ju, et al.	
	3	20060280791	A1	2006-12-14	Ju, et al.	
	4	20070264334	A1	2007-11-15	Ju, et al.	
	5	20070185199	A1	2007-08-09	Ju, et al.	
	6	20070148234	A1	2007-06-28	Ju, et al.	
	7	20070128278	A1	2007-06-07	Ju, et al.	
/SK/	8	20080152714	A1	2008-06-28	Gao, et al.	

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FOREIGN PATENT DOCUMENTS

	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code4	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T5	
/SK/	1	96/19962	wo		1996-07-04	Rosenberg, et al.			

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/SK/	2	96/19963	wo	1996-07-04	Rosenberg, et al.	
	3	98/22094	wo	1998-05-28	Maul, et al.	
	4	99/12526	wo	1999-03-18	Alza Corporation	
	5	99/45887	wo	1999-09-16	Pillay, et al.	
	6	01/34119	wo	2001-05-17	Abbott Laboratories	
	7	02/026214	wo	2002-04-04	Solvay Pharmaceuticals B.V.	
	8	05/013940	wo	2005-02-17	Vanderbist, et al.	
	9	05/046662	wo	2005-05-26	JJ Pharma, Inc.	
	10	06/135480	wo	2006-12-21	Abbott Laboratories	
	11	0240904	EP	1992-07-01	Goertz, et al.	
/SK/	12	0337256	EP	1992-11-19	Klimesch, et al.	

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'SK/	13	0240906	EP	1991-05-02	Klimesch, et al.	
1	14	0358105	EP	1994-03-02	Klimesch, et al.	
	15	0358108	EP	1992-04-15	Plath, et al.	
	16	1157690	EP	2006-08-02	Biovail Laboratories International	
	17	1159419	EP	2005-08-03	Dawson, et al.	
	18	1829541	EP	2007-09-05	Rosenberg, et al.	
	19	19536394	DE	1997-04-03	BASF AG	
100000000000000000000000000000000000000	20	19629753	DE	1998-01-29	BASF AG	
	21	19731277	DE	1999-01-28	Susskind-Schwendi, et al.	
	22	96/016016	wo	1996-05-30	Laboratorios Menarini S.A. et al.	
/SK/	23	1621200	EP	2006-02-01	Fournier Laboratories Ireland Limited	

Application Number 10520505

	Application Number		10000000	
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STATEMENT BY APPLICANT Not for submission under 37 CFR 1.99)	Art Unit		1621	
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		NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
/SK/	1	Arzneimitttel-Forschung 26, 885-909 (1976) - see p. 887	
	2	BASTIN et al., Organic Process Research and Development, Vol. 4, pp. 427-435 (2000)	
	3	FEELY, L.C. & DAVIS S.S., The Influence of polymeric excipients on drug release from hydroxyproprylcellulose matrices," International Journal of Pharmaceutics, Vol. 44, pp. 131-139 (1998)	
	4	FIEDLER, H.B., Lexikon der Eilfsstoffe fir Pharmazie, Kosmetik, and Angrenzende Gebete, 4th Ed., Aulendorf: ECV- Editio-Cantor-Verlag (1996)	
	5	FIKENTSCHER, H., Cellulose-Chemie, Vol. 13, pp. 58-64 and 71-74 (1932)	
	6	FORD, JL., Pharma. Acta. Hely., Vol. 61, pp. 69-88 (1986)	
	7	FROHOFF-HULAMANN, M.A., et al, "Aqueous ethyl cellulose dispersions containing plasticizers of different water solubility and hydroxypropylmethylcellulose as coating material for diffusion pellets II: properties of sprayed films," Eur. J. of Pharm. & Biopharm., Vol. 48(1), pp. 65-75 (1999)	
	8	FROHOFF-HULAMANN, M.A., et al, "Aqueous ethyl cellulose dispersions containing platicizers of different water solubility and hydroxypropylmethylcellulose as coating material for diffusion pellets! Drug release rates from coated pellets," Intri J. of Pharm., Vol. 177(1), pp. 69-82 (1999)	
/SK/	9	Guidance for Industry SUPAC-MR: Modified Release Solid Oral Dosage Forms, U.S. Dept. of Health and Human Serv., FDA, CDER.CMC (8): 1-8-6 (1997)	

Application Number		10539505		
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Art Unit		1621		
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/SK/	10	GURRIERI, J., Antilipidemic Drugs, Arzneim-Forsch (Drug Res.), Vol. 26(5), pp. 890-894 (1976)	
	11	Year is missing Overview of accolic polymer - Fudracit	
/SK/	12	RAO, K.V.R., et al., Zero-Order Release of a Very Soluble Drug From Swelling and Erosion Controlled polymeric Matrices, Contr. Int. Techol. Pharm. 5th, Vol. 5, pp. 242-249 (1989)	
	13	REMINGTON, The Science and Practice of Pharmacy, 19th ed. Table of Contents (1995)	
	14	SUCKER, H., Pharmazeutische Technologie, Thieme-Verlad, Stuttgart (1978)	
	15	TALUKDAR, M.M., et al., Comparative study of xanthan gum and hydroxyproprylmethylcellulose as matrices for controlled-release drug delivery I. Compaction and in vitro drug release behavior, Int'l J. of Pharmaceutics, Vol. 129, pp. 233-241 (1996)	
\downarrow	16	USP Volume 25, Ch. 776 (2002)	
/\$K/	17	XU, D., et al., Influence of ionic strength on drug release from HPMC hydrogel matrix, Chinese Pharm. J., Vol. 23(1), pp. 7-9 (2003)	
	18	Year is missing YE et al. Application of peural petwork in prediction release of insoluble drups from HPMC matrix tablets	
/SK/	19	TOMA, K., Pharm. Ind., Vol. 51, pp. 98-101 (1989)	
/SK/	20	SONG, H., et al., Preparation of the Traditional Chinese Medicine Compound Recipe Heart-Protecting Mush pH Dependent Gradient-Release Pellets, Drug Development and Industrial Pharmacy, 28(10), pp. 1261-1273 (2002)	

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Attorney Docket Numb	er	M/43212-US-1

/SK/	21	CARSTENSEN, J.T., et al., Drug Stability: Principles and Practices, Informa HealthCare, 3rd Edition, p. 316 (2000)	
	22	BERGE et al., Pharmaceutical Salts, J. Pharm. Sci, Vol. 66, No. 1, pp. 1-19 (1977)	
	23	MARGUERY et al., Comparison of the DNA Damage Photoinduced by Fenofibrate and Ketoprofen, Two Phototoxic Drugs of Parent Structure, Photochemistry and Photobiology, 68(S), pp. 679-684 (1998)	
	24	WULFURT et al., Inhibition of Membrane-Bound Hepatic 3-hydroxy-3-methyl glutaryl-CoA Reductase as the Consequence of Altered Membrane Fluidity, Artery, 9(2), pp. 120-131 (1981)	
	25	WALKING et al., Decision Analysis in Drug Product Development, Drug Cosmetic Industry, 112(3), p. 39 (1973)	
	26	DUESEL et al., Substituted Xanthines, Journal of the American Pharmaceutical Association, Vo., 43, Issue 10, page 619 (1954)	
	27	DUESEL et al., Choline Theophyllinate a New Stable Theophylline Derivative of Enhanced Solubility, Int. Rec. Med. Gen. Pract. Clin., Vol. 167, pp. 245-247 (1954)	
	28	MORRIS et al., An Integrated Approach to the Selection of Optimal Salt form for a New Dug Candidate, Int. J. of Pharm., Vol. 105, pp. 209-217 (1994)	
	29	IMPAX LABORATORIES, INC., Paragraph IV Patent Certification Notice, January 26, 2010	
V	30	LUPIN LTD., Paragraph IV Certification, February 9, 2010	
/SK/	31	MYLAN PHARMACEUTICALS, Paragraph IV Certification, March 9, 2010	

(Not for submission under 37 CFR 1.99)

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Attorney Docket Numb	er	M/43212-US-1

/SK/	32	WATSON LABORATORIES, INC FLORIDA, Paragraph IV Certification, March 12, 2010					
/SK/	33	Merck Manual, Vol. 1, pp. 771-780 (1987)					
		Year is missing					
	34	www.americanheart.org/presenter.jbtml?identifier=4600					
/SK/	35	Actavis Elizabeth LLC, Paragraph IV Certification, April 5, 2010					
/SK/	36	Frohoff-Hulamann, M.A. et al., Aqueous ethyl cellulose dispersions containing plasticizers of different water solubility and hydroxypropylmethylcellulose as coating material for diffusion pellets II: properties of sprayed films, Eur. J. of Pharm. & Biopharm., Vol. 48(1), 65-75 (1999)					
/SK/	37	Fournel et al., Xenobiotica, 17, 4, 445-457 (1987)					
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